

# **EXHIBIT 10**

I was asked to develop a Claimant X-ray Study to investigate prevalence of radiographic evidence "consistent with the effects of asbestos exposure, including asbestosis, and cancer" in Claimant X-rays received in response to the attached Orders (Exhibits A, B and C) described in the attached Claimant X-ray Study Protocol (Appendix A).

This initial report focuses on the:

- (1) Claimant X-ray Study design,
- (2) Radiographic evidence of profusion of small opacities in the selected Claimants' X-rays, as reported by,
  - a) 3 independent B-Readers, and
  - b) The Claimant's readers (when available), and
- (3) Control film readings by the 3 independent B-readers.

Additional analyses addressing other radiographic findings as well further statistical analyses of the data presented here are ongoing, and will be included in a subsequent report.

### **Population and File Construction**

According to the responses to the Personal Injury Questionnaires, there were 5,438 Claimants who alleged a non-mesothelioma malignancy caused by a Grace exposure and who were relying on X-ray evidence to support the attribution of their cancer to asbestos exposure. In order for me to complete my study, Grace asked that all such Claimants send in their original chest X-rays.

As a result of this request and several court orders that followed, we eventually received by the submission deadline of March 15, 2007, 3,268 X-rays that were either original X-rays or copies of X-rays and that were accompanied by the necessary certification. (An additional 1,105 X-rays were not accompanied by the required certification, and 293 X-rays were sent after the March 15 deadline.) Of the 3,268 compliant submissions, a total of 3,132 Claimants had at least 1 erect posterior-anterior ("PA") X-ray that met the study's specifications. These were submitted by a total of 48 Law Firms, with more than 2/3 of the Claimants' X-rays received after March 9, 2007. Over the next 30 days, the attached protocol (Appendix B: PIQ X-ray Protocol 3-11-07) was implemented to record each Claimant's demographics and the specifics of their last X-ray, and to redact their last X-ray.

In addition to a PA X-ray, the study protocol required each Claimant's date of birth or age at X-ray, gender, and the date of their X-ray. A total of 2,857 Claimants, from 47 Law Firms, had this information contained in their Personal Injury Questionnaires or on

their X-ray, and those Claimants were included in the total sample pool from which the study samples were drawn.

Of these 2,857 Claimants, only 2,451 had initially been identified as complying with the Orders. Accordingly, on April 10, 2007, Claimants were selected from this first group of 2451 to satisfy two sample pools: (1) those that, according to the Claimants' Personal Injury Questionnaires, had an ILO (International Labor Office Reading) accompanying their X-ray (ILO Firms Sample n=500), and (2) those with X-rays, but irrespective of their having an accompanying ILO reading (All Firms Sample n=500). These samples were designed to allow for:

- (1) The comparison of radiographic abnormalities between 3 independent B-readers' ILO readings and the Claimants' readers' ILO readings, for X-rays submitted with an ILO reading, and
- (2) The assessment of prevalence of radiographic findings across all Law Firms, by the 3 independent B-readers, irrespective of whether an ILO reading was submitted with the X-ray.

There was overlap between the samples, and two pools were needed to be inclusive of all Law Firms, because not all Law Firms submitted Claimant X-rays with an ILO reading. These samples were drawn, without any knowledge of specific radiographic findings, according to the Claimant X-ray Study Protocol described in Appendix A. In brief, a proportionate random sample of all qualifying Law Firms submitting Claimant X-rays with an ILO reading was first selected for the ILO Firms Sample. If the number of previously selected X-rays were insufficient to meet the proportion for the All Firms Sample, additional X-rays were randomly selected to complete their proportion. The proportion was based on the number of Claimants each Law Firm submitted, with and irrespective of an ILO reading. In order to maximize inclusion of all Law Firms in both cases, at least 1 X-ray and 1 X-ray ILO match, when available, were added to the pools for any Law Firms not represented in both pools.

On April 15, 2007, 406 additional Claimants were identified as complying with the Orders (having certified the copies of their X-rays), bringing the total from 2451 to 2857. These additional Claimants were added to the total population pool, and two additional samples were drawn as described above.

These two sample draws produced final overlapping samples that were greater than 500 each, but they were not scaled back because the additional inclusion criteria, noted below, had not yet been validated. This was done to provide samples of appropriate size.

#### **Inclusion Criteria & Validation Developed From PI Questionnaires**

To assure that the selected study X-rays (multiple X-rays were included for many Claimants) were the last pre-operative (lung surgery) or pre-radiation/chemotherapy

films, so as to include relevant evidence of abnormality in support of their claim, a sample validation protocol and an associated flow chart for implementation of the protocol was developed. (See attached Claimant X-ray Study Protocol in Appendix A, and the attached Sample Validation Flow Chart in Exhibit D.) In addition, only PA-view original, copy or digitally generated chest X-rays were included in the samples. Miniature X-ray images, X-rays that were available only on CD, or CT (computed tomography) or HRCT (high resolution computed tomography) scans were excluded.

On April 10-11, 2007, a B-reader validated the X-rays selected for inclusion on April 10, and on April 19, 2007, a B-reader validated the X-rays selected for inclusion on April 15. For both validations, only the above criteria were applied, and there was no consideration of any radiographic finding. If the originally selected X-ray failed to meet the criteria, a replacement film for a given Claimant, or, if necessary, a replacement Claimant, was selected according to Exhibit D. It should be noted that fewer than 10% of the selected Claimant X-rays failed this validation. In addition, though the samples were still larger than originally intended, due to the late inclusion of 4 additional law firms and their sampled Claimants, it was again decided not to scale any of the samples back to their original size, because:

- (1) The larger samples would be more representative of the whole; and
- (2) The ILO sample was based on information from the Personal Injury Questionnaires indicating that ILO readings were provided, though the actual existence of any ILO readings had not yet been validated.

### **Population Pools and Samples**

The attached spreadsheet (Appendix C: Eligible Claimant Pools and Samples Final Version) describes the various population pools and whether a specific Claimant and Law Firm met the final inclusion criteria (readable pre-treatment PA view X-rays, with or without associated Claimant submitted ILO readings), and were selected for the study. The spreadsheet is sorted vertically in alphabetical order, first by Law Firm (column E), and then by Claimant's last name (column C). Also shown are ID numbers (columns A and B) and the Claimant's SSN when provided (column D). The various populations, percent participation and samples are shown in columns F – L, and are described as follows:

- Column F, labeled Total Sample Pool, identifies all eligible Claimants (N=2,857) prior to validation from all Law Firms (N=47), shown as YES.
- Column G, labeled Claimants In Total Sample, identifies the 807 Claimants from 40 Law Firms that meet inclusion criteria (readable pre-operative PA view X-rays irrespective of a provided ILO), shown as YES. A total of 7 Law Firms, in column F, and all of their 10 Claimants did not meet the inclusion criteria.
- Column H, labeled Firm's % Participation in Total Sample, shows the percent of each of the 40 firms Claimants that met the inclusion criteria and were selected

for the Total Sample (note that this is a combination of the All Firms and ILO Firms sample). The participation ranged from 16.67% to 66.67%. The larger percentages are the result of including at least 1 Claimant for all firms, and in attempting to find 500 Claimants whose X-rays actually had an ILO reading (see column L described below).

- Column I, labeled Claimants in All Firms Sample, identifies the 507 Claimants, shown as YES, from 40 Law Firms that meet inclusion criteria. These 507 Claimants were randomly selected from the 807 to provide a sample more proportionate of the Claimants submitted per Law Firm. The Total Sample population of 807 claimants was sorted by Law Firm, and each Claimant in a given Law Firm was randomly assigned to a sequential ID number (1 to number of Claimants within a given firm; *i.e.*, if a firm had 20 Claimants, the ID numbers were 1 through 20). The number of required participants per firm was calculated ( $.175 \times$  total number Claimants within a firm). If the Claimant ID was less than or equal to the number of required participants, that Claimant was selected, if available, for a total of 507.
- Column J, Labeled Firm's % Participation in All Firms Sample, shows the percent of each of the 40 Law Firm's Claimants that met the inclusion criteria and were selected for the All Firms Sample. The participation ranged from 16.67% to 50%, with the inclusion of the 11 firms submitting between 2 to 19 Claimants having a percentage  $\geq 20\%$ .
- Column K, labeled Claimants in ILO Sample Pool, identifies the 947 Claimants from 31 Law Firms, shown as YES, that were reported to have an X-ray accompanied by an ILO, according to the submitted documentation.
- Column L, labeled Claimants in ILO Firms Sample, shows the 471 Claimants from 28 Law Firms with an X-ray and accompanying ILO reading that met the inclusion criteria and were selected for the ILO comparison study, shown as YES. Three Law Firms in column K did not have a Claimant X-ray meeting the inclusion criteria. Though more than 500 Claimants with an associated X-ray and ILO were initially sampled for inclusion, some of the ILO forms were illegible, not filled in, partly obliterated, or did not actually exist in the database. In addition, some X-rays associated with ILOs were of poor technical quality or post-operative, and some substituted X-rays did not have an associated ILO. In addition, some claimants did not have an X-ray with an associated ILO form. However, some of the Claimants initially sampled or other Claimants not initially sampled, who, according to their submitted documentation, did not have an ILO reading, in reality had an ILO form among the attachments to the Questionnaire or included an ILO form in the X-ray jacket and were included and resulted in the 471 Claimants shown here. Of these 471, 463 had an ILO reading for the selected X-ray, and 8 had an ILO reading for an earlier X-ray.

The above resulted in a Total Sample of 807 Claimants from 40 Law Firms, an All Firms Sample of 507 Claimants from 40 Law Firms, and an ILO Firms Sample of 471 Claimants from 28 Law Firms.

### **Study Readers & Readings**

Three experienced independent B-readers were selected for the study. Dr. Robert Tarver is an academic pulmonary radiologist and full-time faculty member at Indiana University (Reader A). Dr. Lee Sider is an academic pulmonary radiologist and full-time faculty member at Beth Israel Medical Center and a member of the American College of Radiology Pneumoconiosis Committee, who also consults for NIOSH (Reader B). Dr. John Parker is an academic pulmonologist and full-time faculty member at West Virginia University. Dr. Parker is a former member of the ACR Pneumoconiosis Committee and was the "third reader" in the ATSDR Screening Study in Libby, Montana (Reader C). The CVs for all three readers are attached to this report. The use of three readers has been validated in a previous report (Lefante J, Hughes J, Jones R, Weill H. *An Analysis of X-Ray Reader Agreement: Do Five Readers Significantly Increase Reader Classification Reliability Over That of Three Readers? Proceedings of the VIIth International Pneumoconioses Conference, Part I. DHHS (NIOSH) Publication Number 90-108. Washington, D.C.: Government Printing Office, 1990, pp. 482-486.*). The report concluded, "When using three experienced readers (the widely accepted minimum for epidemiologic research), the effect of including two additional readers seems to be negligible . . . enlarging the panel to five members is unlikely to affect median small opacity profusion."

Between April 20 and April 29, the 3 independent B-readers (blinded with respect to the source of the X-rays, the purpose of the study, and the entity on whose behalf they were reading the X-rays) separately classified all 807 study X-rays in addition to 47 normal and abnormal control films. The readers' observations were recorded on a "Pneumoconiosis Surveillance Evaluation" Study ILO B-reading Form attached (Exhibit E) that is consistent with the 2000 ILO Guidelines. As noted above, only PA-view chest X-rays were read, and the images included original films, copy films, and digitally generated films, but miniaturized X-ray images or X-rays that are available only on CD were not included, nor were CT or HRCT scans. The B-reading Forms and X-rays were pre-marked with a unique ID number for each Claimant along with the date of the X-ray being evaluated, but all other identifiers were redacted.

### **Results**

The results shown below address the following:

- (1) ILO profusion readings  $\geq 1/0$  by the 3 independent B-readers and by the Claimants' readers, when ILO readings were provided, for the Total, All Firms and ILO Firms samples,  $n=807$ , 507 and 471, respectively, and
- (2) Control film readings by the 3 independent B-readers,  $n=47$ .

***ILO Profusion of Small Opacities  $\geq 1/0$*** 

The attached spreadsheet (Appendix D: Claimant's Profusion) is sorted vertically in alphabetical order, first by Law Firm (column E), and then by Claimant's last name (column C). Also shown are ID numbers (columns A and B) and the Claimant's SSN when provided (column D). The various populations and reported profusion  $\geq 1/0$  are shown in columns F – K, and are described as follows:

- Column F, labeled Claimants In Total Sample, shows that all 807 are in the total sample previously described.
- Column G, labeled 2 of 3 Ind B-Rdrs Prof  $> 1/0$  In Total Sample, indicates for these 807 whether or not at least 2 of the 3 independent B-readers reported profusion  $> 1/0$ .
- Column H, labeled Claimants In All Firms Sample, identifies the 507 Claimants in this sample that was previously described.
- Column I, labeled 2 of 3 Ind B-Rdrs Prof  $> 1/0$  In All Firms Sample, indicates for these 507 whether or not at least 2 of the 3 independent B-readers reported profusion  $> 1/0$ .
- Column J, labeled Claimants In ILO Firms Sample, identifies the 471 Claimants in this sample that was previously described.
- Column K, labeled Claimant Rdrs Prof  $> 1/0$  In ILO Firms Sample, indicates for these 471 whether or not the Claimant readers reported profusion  $> 1/0$ .

These results are summarized in the following table.

Samples	N	3 Independent B-Readers		Claimant Readers	
		Profusion $\geq 1/0$	Percent	Profusion $\geq 1/0$	Percent
ILO Firms Sample	471	33	7.01%	383	81.31%
All Firms Sample	507	37	7.30%		
Claimants Without ILO	336	24	7.14%		
All Selected Claimants	807	57	7.06%		

It should be noted that all 3 independent B-readers read the same X-ray for each Claimant-submitted ILO reading as the Claimants' readers read. In 8 cases noted in

column K of Appendix D, the 3 independent B-readers read a different X-ray than the Claimants' readers' read. In these 8 cases, the X-ray that corresponded with the Claimants' readers' read was not produced, but a later X-ray was available, so the 3 independent readers read a X-ray generated after the X-ray read by the Claimants' readers. These were included in the above analyses since all X-rays read by the 3 independent B-readers were pre-operative, and any profusion noted in an earlier X-ray by the Claimants' reader should still be evident in a later pre-operative X-ray.

As noted in the table, the percent positive profusion among the 3 independent B-readers was always approximately 7%, irrespective of whether there existed a Claimant-provided ILO. Also, 13 Claimants did not have a positive profusion by at least 2 independent B-readers, because one or more readers thought a given X-ray was unreadable (identified in column G and I of Appendix D with an asterisk). Excluding these readings, the percent of Claimants with a positive profusion finding by at least 2 of the 3 independent B-readers still did not exceed 7.5% in any of the samples. In any event, the Claimants' readers reported more than 11 times the number of Claimants with profusion  $\geq 1/0$  than did 2 of the 3 independent B-readers.

#### ***Independent B-Readers' Control Readings***

A total of 47 control films were selected by the author. These included 25 negative and 22 positive films. The results are shown in Appendix E: Control Film Readings by 3 independent B-Readers.

The kappa statistic, sensitivity (likelihood that a positive film will be correctly classified as positive), and specificity (likelihood that a negative film will be correctly classified as negative) were computed for the majority reading and for each of the 3 independent B-readers. The kappa statistic compares agreement against that which might be expected by chance, and can be thought of as the chance-corrected proportional agreement with possible values ranging from +1 (perfect agreement) to 0 (no agreement above that expected by chance) to -1 (complete disagreement). A rough guide to agreement is provided below. (Landis and Koch, *The Measurement of Observer Agreement for Categorical Data*, Biometrics, Vol. 33, No. 1 March 1977 at page 165.)

Kappa	Strength of agreement
0.00	Poor
0.01-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial



<b>0.81-1.00</b>	<b>Almost perfect</b>
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The results are shown in the following table, along with the 95% confidence interval for the kappa statistic shown in parentheses. The majority agreement of 0.74 was well within the substantial agreement range. All three readers had moderate to substantial agreement with controls. The majority readings had similar high sensitivity and specificity, correctly classifying positive films as positive and negative films as negative more than 85% of the time.

	<b>25 Negative and 22 Positive films</b>		
	<b>Kappa</b>	<b>Sensitivity (+ as +)</b>	<b>Specificity (- as -)</b>
<b>Majority</b>	<b>0.74 (0.55-0.94)</b>	<b>86%</b>	<b>88%</b>
<b>Reader A</b>	<b>0.58 (0.35-0.81)</b>	<b>86%</b>	<b>86%</b>
<b>Reader B</b>	<b>0.70 (0.49-0.90)</b>	<b>77%</b>	<b>92%</b>
<b>Reader C</b>	<b>0.54 (0.31-0.77)</b>	<b>91%</b>	<b>64%</b>

## Conclusion

The results presented above show that the Claimants' readers reported profusion of small opacities ( $\geq 1/0$ ) in 383 (81%) of 471 Claimants. This was 11 times more frequent than the majority readings of the 3 independent B-readers who reported profusion in only 33 (about 7%) of these same Claimants. Similar positive proportions (approximately 7%) were reported by the majority readings of the 3 independent B-Readers for the 336 Claimants whose X-rays were not submitted with an ILO reading.

These results are consistent with a previous report (Gitlin JN, Cook LL, Linton OW, Garrett-Mayer E., *Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos Related Changes*. *Academic Radiology*, Vol 11, No 8, August 2004, pp. 843-856). They reported on 492 cases where plaintiff-selected readers over-reported profusion by a factor of 21.3, as compared to 6 independent readers (95.9 % v 4.5% positive for profusion  $\geq 1/0$ ). This study was referenced in my original October 3, 2006 expert report.

Further validation of the majority readings of the 3 independent B-readers is provided in the kappa statistic, and sensitivity and specificity of the control readings. The majority agreement was well within the substantial agreement range, and the specificity and sensitivity indicated that the majority reading correctly identified both normal and abnormal control films more than 85% of the time. (Landis at page 165.)

Therefore, it is my professional opinion that the profusion results submitted on behalf of the Claimants substantially overestimate, by a factor of approximately 11:1, the actual prevalence of radiographic abnormalities present in the study population. The differences in results from the independent readers (7% 1/0 or greater) and the Claimants' readers (81% 1/0 or greater) cannot be accounted for based simply on inter-reader variability. The results from the independent readers are more accurate and reliable than the aggregate results of the Claimants' readers for a number of reasons. First, the three B-readers in this study are skilled academic physicians and recognized as experts in thoracic imaging or the imaging of occupational lung disease. Second, this study was fashioned in a manner that was consistent with both the ILO and NIOSH guidelines. For example, the B-readers were recruited, and the study was constructed, in a manner such that the readers were blinded to the identity of the client for whom they were reading the X-rays. Next, the use of control films (unknown to the independent readers) allows for the statistical evaluation of the readers' reading tendencies, which, given the results of the control film reads, demonstrates that the readers are not inclined to significantly over- or under-read X-rays. Finally, both the ILO and NIOSH Guidelines recommending the use of three independent readers to generate more reliable results were employed.

  
Dr. Daniel Henry

6-11-07  
Date